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# Interim Report on Quality Assurance to the Environmental Protection Agency

National Research Council, Washington, DC

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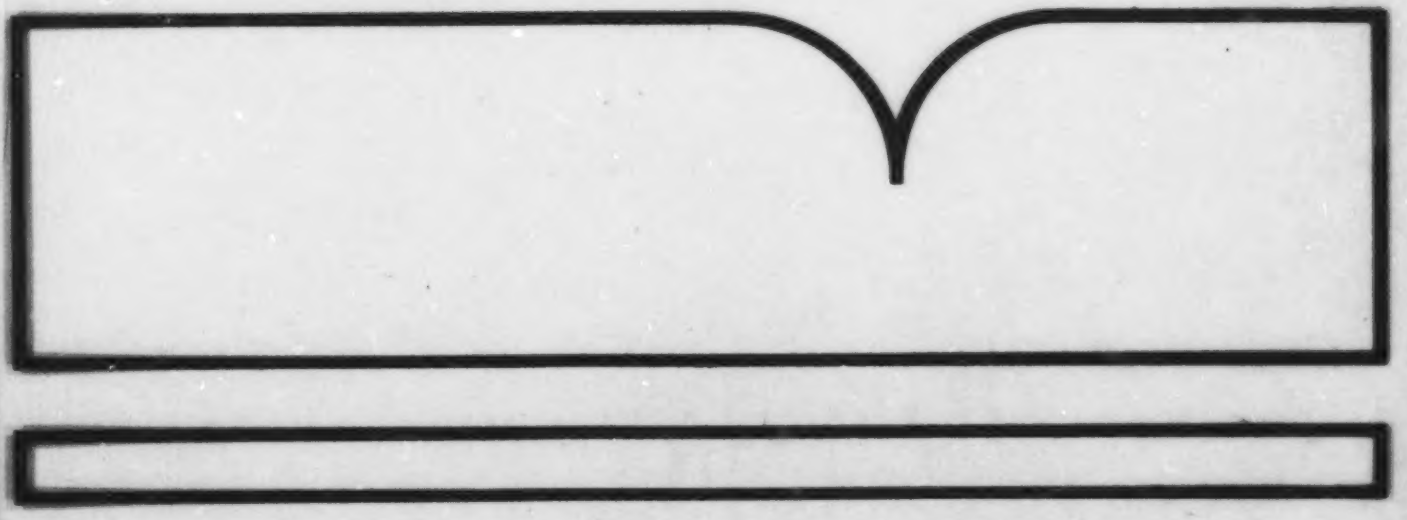

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# Interim Report on Quality Assurance to the Environmental Protection Agency

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The panel's study is now essentially half done. The document in hand is an interim report to provide EPA with the findings that the panel has arrived at thus far and the recommendations it can firmly make on the basis of those findings. The interim report sets out matters that the panel believes can be addressed now by EPA, independently of other matters intended for the final report.

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# INTERIM REPORT
# ON QUALITY ASSURANCE
# to the
# ENVIRONMENTAL PROTECTION AGENCY

Panel on Quality of Environmental Data
Numerical Data Advisory Board
Commission on Physical Sciences, Mathematics, and Resources
National Research Council

NATIONAL ACADEMY PRESS
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This report has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee consisting of members of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

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# I INTRODUCTION

In April 1983 the Environmental Protection Agency (EPA) contracted with the National Academy of Sciences (NAS) to review the Agency's control of the quality of its scientific data, and particularly its Quality Assurance (QA) program. The contract implemented an initiative of 1980 by the EPA requesting assistance from the National Academy of Sciences (NAS). The NAS delegated the responsibility to its operating arm, the National Research Council (NRC), which, in turn, called upon its own Numerical Data Advisory Board (NDAB) to carry out the task. To conduct the requested assistance and review, the NDAB established a panel of six scientists--with recognized expertise in one or more relevant fields--to work with EPA, under the guidance of the NDAB, for three years, to (1) engage in discussions and briefings to help the EPA establish a sound QA program, (2) review methods, methodology, and selected key EPA QA documents, and (3) present its findings and recommendations. The final report is to be distributed as an advisory document that EPA could use to strengthen its programs, particularly those involving numerical scientific data.

The panel's study is now essentially half done. The document in hand is an interim report to provide EPA with the findings that the panel has arrived at thus far and the recommendations it can firmly make on the basis of those findings. The interim report sets out matters that the panel believes can be addressed now by EPA, independently of other matters intended for the final report.

Three topics are discussed here:

1. structural problems: what are the roles of quality control (QC) and quality assurance (QA) in EPA, and what do these roles imply? Why have a quality assurance program, and who is it for?
2. specification of objectives: how can "adequate" quality of data be determined and what should a QA program and QC accomplish?
3. management of budgeting, staffing, and documentation for EPA's quality assurance program: how can the aims of the two previous questions best be achieved?

These topics are not the only issues that have concerned the panel, but they are the ones regarding which the panel feels sufficiently informed to make statements at this time. These and other matters will be covered in the final report.

Before turning to the body of the report, the panel would like to make explicit two fundamental assumptions that have guided it. Mentioning the first seems obtuse, but it is no less important for being obvious:

1. Scientific data gathered by, for, or under the auspices of EPA are used for purposes requiring specific levels of known validity of those data.
2. A clear line of accountability is in place so that the lines of responsibility for scientific data quality are known to all participants in the relevant EPA activities.

Without clear lines of accountability, a quality assurance program for scientific data is ineffective. If scientific questions were the only ones EPA faced, it might be possible for EPA to leave such accountability diffuse or undefined and rely on professional standards of data quality control. However, EPA's responsibilities are to the public to protect its health and the quality of the environment. Consequently, the panel considers such an informal course inconsistent with implications of EPA Order 5360.1 labeled "Policy and Program Requirements to Implement the Quality Assurance Program." The panel agrees with this Order, that the matter of accountability must be examined by the EPA administrator, in order for the Agency to fulfill its responsibilities. So long as there is accountability for failure to maintain specified levels of data quality, the service performed by a QA program in EPA becomes essential.

## II. STRUCTURAL PROBLEMS: THE ROLES OF QUALITY CONTROL AND QUALITY ASSURANCE IN EPA

Quality control (QC) and quality assurance (QA) are instruments used by institutions to maintain the quality of the goods or services those institutions provide at the level desired by the institutions' managers. QC encompasses all the means by which line workers achieve and maintain a desired level of quality in the products. QA consists of the means used by the institutions' managers to guarantee to their own satisfaction that the quality of the products is indeed being maintained at the desired level and at the level claimed by the line workers. These two functions are widely recognized and distinguished. The former is the consequence of the skill and sense of responsibility of a professional carrying out a task conscientiously. The latter is a kind of insurance that management constructs to protect itself and its institution against failures or weaknesses in QC. It is predicated on accountability for such failures and weaknesses.

To see what these functions mean in the context of EPA, it is useful to draw parallels with the pre-1984 Bell System, which had a highly developed QA program. In some respects the parallels are limited, but they provide a useful starting point. Understanding what QC and QA are requires identifying the suppliers, the goods, and the customers. In the Bell System, the suppliers were the manufacturers of telephone equipment and those who maintained the operation of the telephone system. The intermediate goods were devices and operations; the ultimate goods, telecommunication services. The customers were of two kinds: intermediate customers, including the Western Electric plants in which the devices were made and the operating companies that bought and sold devices; and ultimate customers, the customers purchasing the telephone services or ultimate goods.

In the EPA, the suppliers are those who provide environmental data, and the intermediate goods are the data themselves. The intermediate customers are the compliance officials of EPA and others, such as researchers within EPA and outside and people drafting proposed regulations and laws for environmental management, whether in EPA, in Congress, or in the private world. The data (intermediate products) are used by the intermediate customer to produce the ultimate product of environmental protection and enhancement to the ultimate consumer, the taxpayer. Environmental protection is achieved by deciding what the data mean and taking actions appropriate to that meaning.

QC in EPA must thus be equated with the means the suppliers of data use to check and control the quality of those data, through control over all the technical aspects of their work, beginning with decisions about what, where, when, and how to sample, going through analyses of samples, to maintenance of the integrity of lines of custody and data storage, and, finally, to documentation of the data. A QA program constitutes the activities of oversight and monitoring that ensure that the quality of the data does indeed meet the expectations of its intermediate customers. The purpose of the QA program, crassly put, is to prevent any embarrassing situation in which the data fail to serve their intended function because their quality turns out to be too far from what was expected. Stated more generously, QA for data in EPA is the certification, independent of the data supplier, that those data are adequate for their intended purposes.

Within EPA, the panel found some offices where the distinction between QC and QA is clearly understood. In other parts of the Agency, the distinction between the two activities was not so clearly understood. Nowhere in the parts of EPA visited by the panel did the panel feel that the roles of the participants were distinguished enough for the two functions to be carried out in a healthy, complementary way. One specific recommendation of the panel is as follows: *The roles of quality control and quality assurance should be clearly understood throughout EPA, and implemented in a manner that keeps the two clearly separated.*

QC is primarily a technical matter of sound scientific practices. QA is also partly technical but at least equally institutional. That aspect is discussed in more detail here.

Because QA is a service to management, specifically a kind of protective insurance, any QA program must have certain characteristics:

1. Independence from those groups whose performance it is scrutinizing.
2. Technical competence and ability to evaluate and assist those groups.
3. Clearly understood authority.
4. Vigorous management.

These characteristics have emerged from many years of industrial experience with QA programs. The panel is persuaded that the same characteristics are required for a successful QA program in EPA.

In the Bell System, there was a single QA program, integrated throughout the system and headquartered in Bell Laboratories. The QA personnel reported to the central management of the Bell System; the perception was that it was the managers of the System who were being served by the QA staff.

EPA is quite a different sort of institution. Many of its activities and responsibilities go on in regional administrations or laboratories. The structure of the Agency and the distribution of responsibilities within it differs enough from most private firms that the panel felt that it should not make a *simple, explicit* recommendation regarding the structure of the Agency's QA program. However, the panel

does make a very strong recommendation, one that it feels is one of its most important, regarding the structure of EPA's QA program: *The administrator must determine who it is that the quality assurance program should be serving and protecting, and design the program so that it carries out that function.*

The panel has drawn up two options for EPA's QA program that it considers viable, and has described a third situation, corresponding to the status quo, that it believes cannot achieve the purposes of a QA program.

Option 1: In each assistant administrator's office associated with an EPA program there would be a chief QA Officer (QAO) responsible for QA in that program throughout the Agency. The person served by that QAO and those QA staff reporting to that QAO would be the assistant administrator. QA staff members from each program office would be located in each region and relevant Environmental Monitoring Systems Laboratory (EMSL) to assure the assistant administrator of the program of the quality of data. A headquarters QA staff would be maintained in a form similar to the present Quality Assurance Management Staff (QAMS), with responsibilities for coordination, Agency-wide guidelines, procedures, and audits. In this option, the number of individuals to be associated with QA in the program offices and central QAMS staff should probably be roughly half the present number of full-time equivalents (FTE) identified with QA activities. The regional directors and other senior staff would be free to establish their own QA programs, in manners that they would see as protecting them. To assist the implementation of this option, uniform documentation of recommended QA and QC practices should be widely available to all branches of EPA and to its contractors.

This first option is based on the panel's understanding that in EPA, as it now functions, the principal data users--enforcement staffs, drafters of standards and regulations, and analyzers of trends--work within the specific program offices and get any data they need from suppliers primarily in that same program office. The option is drawn on the supposition that the assistant administrator for each program would be the person accountable for a failure in performance due to inadequate or misrepresented data quality. It is the panel's impression that the regional administrators might also be accountable for such failures within their own regions and would consequently find it very much to their own advantage to establish their own QA programs. The panel would strongly recommend that the regional administrators use funds under their control for this purpose.

In the case of the assistant administrators for programs, the panel recommends that the establishment of QA activity for the programs be mandatory and not optional, for the following reason. While the assistant administrators can be accountable to the administrator for program inadequacies, the person ultimately accountable as a public official is the administrator. Short of going to the second option (below), it seems to the panel that the administrator must mandate the effective operation of QA activities centered at the program level as insurance of the integrity of the Agency.

The third Section of this report returns to the matter of specific forms of management for this option. It is the option that the panel believes most effectively meets the aims of a QA program within the style of governance that places responsibility and authority at the lowest level where it will be effective.

Option 2: This option is predicated on a supposition that much of EPA's scientific data is used in parts of the Agency well separated from those parts responsible for gathering and evaluating data. If this is the case, the panel recommends centralization of the primary responsibilities for QA so that the chief QAO reports directly to someone in the administrator's office. In the model supposed for this option, which the panel believes did apply to EPA for some time, there is nobody below the level of the administrator's office who could be held accountable by the intermediate and ultimate data users for a failure due to inadequate or inadequately represented data quality. It would be the administrator who would need the assurance that one side of the house was supplying goods as specified to the users on the other side.

According to this option, lines of responsibility would run from the chief QAO to all the program offices, regional offices, and EMSLs. Unless a large part of the use of scientific data occurs in offices well separated from data collection, such as the Office of Enforcement and Compliance Monitoring, the panel would recommend against this option, in favor of the first.

The third situation, which we do not consider a serious option, is to maintain the status quo in the QA program, with responsibilities delegated in terms of performance at the lowest level of management. The panel considers this unacceptable because it creates self-contradictory, self-defeating situations that are likely to thwart the purposes of QA. By defining (implicitly) the performance of QA activities at the low levels where these responsibilities frequently fall now, EPA has exposed a confusion between QC and QA. The function of QC is indeed carried out, and properly so, at the level of the sampling, laboratory testing, sample handling, transmission and storage, and data analysis. The function of QA is an activity of service directly to a manager at some well-defined level of accountability. In Option 1, this is the level of the assistant administrators. In allowing responsibility for "quality assurance" to be distributed all the way to the level of laboratory directors, EPA has at present put the responsibility for surveillance and auditing into the hands of those who are being surveyed and audited. By allowing managers to make their QAOs part-time, QA personnel become part-time objects of review by the QA staff, i.e., by themselves. There is nothing wrong with having some people work part time in support of QA, but it is altogether incompatible with the function of a responsible QA officer to have loyalties divided between the manager being served by the QA function and the bench supervisor whom that manager oversees. The panel urges very strongly that the present structure be transformed as rapidly as can be done smoothly into one of the other options, preferably Option 1.

Whatever option is chosen, it is important that the QA staff are seen not only as police but also as skilled, helpful technical counsels to those whom they oversee. Policing and helpful counseling may appear to be incompatible roles but in practice, well-managed and staffed QA programs succeed in combining these tasks. Industrial experience has proven that this dual role can be carried out successfully. The panel sees no reason why it should not work in EPA.

One issue has come to the attention of the panel through its own interactions with EPA and through previous studies of the Agency. This is the difficulty the Agency has had with determining what constitutes "adequate" data in crisis situations. To cope with unpredictable crises, it is inefficient to try to maintain a permanent staff. Nevertheless, a high level of expertise is usually required to make a sound judgment in such situations. A standing board of expert scientists and engineers functioning as a "volunteer fire department" might alleviate this longstanding problem.

On this matter, the panel specifically recommends that within the structure of the QC and QA programs: *The EPA should establish a means to call up "crisis panels" of experts to advise on quality control and quality assurance in emergency or short-term extreme situations.*

The experience of the Agency with such "crises" in recent years indicates what value such panels would have. It would be relatively simple to maintain contact with rotating groups of outside experts willing to serve in emergency situations, groups who would function like volunteer fire departments and who could give the Agency guidance and credibility when needed.

## III. SPECIFICATION OF OBJECTIVES: THE PURPOSE OF DATA

*EPA must translate the scientific and regulatory objectives of programs that acquire environmental monitoring data into specific requirements for quality assurance and quality control.*

Virtually every guideline and statement of QA principles and procedures issued by EPA officials and by QAMS over the past five years mentions the need to define the purpose of each environmental monitoring effort and therefrom derive requirements for the quality of the data. However, until the issuance by the deputy administrator of the May 24, 1984, memo on Data Quality Objectives, negligible emphasis had been given to this critical step in defining a QA program. None of the many QA program and project plans (including so-called model plans) that the panel has reviewed address this subject in a meaningful way; in fact, most totally ignore it.

For example, the Las Vegas EMSL is nominally responsible for QA and QC in support of the Superfund program. In point of fact, their QA and QC procedures are developed in a consensus forum by representatives from the contractor laboratories, regions, and headquarters Superfund staff without any significant input from the principal end-user, namely, the enforcement division of the Superfund Office. To quote one senior EMSL staff member: "We are somewhat blind to the end use of the data."

For example, the General Accounting Office Report, "Underlying Problems in Air Quality Monitoring Systems Affect Data Reliability" (GAO/CED-82-101, September 1982), places great emphasis on the importance of EPA's need for "accurate, reliable air quality data," and points to a lack of resources devoted by the federal EPA and the states to QA. In the GAO report the EPA counters that the National Air Monitoring Station network is "complete" and that current procedures are adequate for directing federal and state resources to QA. However, nowhere in this discourse is any attention paid to (1) the basis upon which the network itself was established, (2) current and anticipated future requirements for such data, and (3) the status of QA/QC efforts in terms of such needs.

For example, the Great Lakes Atmospheric Deposition (GLAD) network has been collecting wet and dry samples since the late 1970s, and plans are under way to expand the network. An impressive set of QC procedures are in place. Yet, there appears to be no documented scientific or regulatory rationale behind the network layout, sampling criteria, and specific QA/QC protocols.

The panel's reviews of headquarters programs, regional offices, and field laboratories consistently confirm this disregard of the purpose of environmental monitoring data and lack of critical user input in establishing related QA programs and QC protocols. The QAMS requirement that a QA plan be developed for each major program and research project is being met by the field offices and major EPA contractors. The panel has been told that several of the latter have set up special offices in Research Triangle Park, North Carolina, to generate such plans. Yet those plans reviewed by the panel uniformly begin with a statement of data requirements, void of any supporting rationale based on the ultimate purpose of the data.

There has been within EPA among line managers in headquarters and the field a widespread lack of support for QAMS and its QA directives. There has been, correspondingly, a reluctance to allocate adequate resources for QA and to provide adequate authority for those responsible for QA. The panel believes that the root of such attitudes is the lack of clear coupling between the objectives of the line regulatory programs and the imposed requirements for QA and QC. As long as there is no more than a vague understanding by the line management of the rationale behind the QA program and its specific directives, this situation will persist. Without well-understood objectives for data quality, QAMS lacks the necessary foundation for its whole program, so that its goal becomes assuring "data of known quality" instead of "data of appropriate quality." The former may have to suffice as an interim, pragmatic objective but must not be the long-term goal of EPA's data activities.

The panel is very much encouraged by the recent QAMS initiative to work with the programmatic assistant administrators and their senior staff in the development of "data quality objectives" for all significant environmental measurement activities, and it looks forward over the coming year to the opportunity to observe the progress of this critical effort. The panel emphasizes the importance of each of the following five steps:

*1. The QAMS guidelines should be revised to place much greater emphasis on the requirement for a systematic analysis of the purposes of the project or program and of the data to be acquired, whether the data used be of legislative and regulatory or scientific and interdisciplinary nature.*

*2. A guideline for carrying out such analyses and for deriving specific QA and QC activities should be prepared by the QAMS management.*

*3. Prototypical project and program QA plans should be developed jointly by the program offices and QAMS to demonstrate the above.*

*4. A realistic schedule should be established to evaluate all major ongoing environmental monitoring networks in these terms.*

*5. The EPA QA program should be structured so that the assistant administrators responsible for individual regulatory programs have as one principal measure of their performance the implementation of effective QA programs for environmental monitoring data, where such QA activities derive from an understanding of the ultimate purposes of the data.*

## IV. BUDGET AND STAFF

The need for strong QA programs has been recognized by the EPA, although it is evident that many of the operating sections of the EPA have not yet assimilated this realization or determined the best manner in which to organize, and to benefit from, a strong QA program. There are probably several reasons for this. QA at EPA appears to have developed in response to a mandate that each program within the Agency must have its own QA program; in some cases these were added easily, without extensive change; in other cases, the transition was not so easy. The principal client of the program is not well identified in many cases, as is pointed out in Section I. This situation can lead to the development of a less-than-constructive adversary relationship between the QA officer and the Agency line personnel, unless the QA program is organized to protect the QA officer when she or he is in the vigorous pursuit of some well-recognized QA problem.

Of serious concern to the panel is the question of the adequacy of the Agency's financial commitment to the QA program as a result of the decentralization of responsibilities for QA. It appears to the panel that, in too many cases, the QA program has been treated as a meaningless, burdensome, bureaucratic formality. Because the QA budget must be derived from the existing program budget, which may have been planned without QA in mind, the responsible assistant administrator in some cases sees the QA program as undesirable baggage, competing with the "real" activity of his or her program. In some cases the panel has encountered very high quality in the designated QA officers; in other cases, the appointments appear to have been made to individuals who may not have fit in well elsewhere; such QA appointments served as convenient "dumping grounds." It is evident that if a QA program is to be of maximum benefit to the Agency, the personnel appointed to the QA officer positions must be highly enough qualified in the major areas of interest to his or her particular office or laboratory to have the respect of the people they advise and monitor. As the panel has stated previously, it is important that the QA officers be independent of the groups for which they have oversight and report to the individuals who seek the protection of the QA program (e.g., the assistant administrators). They must be on the payroll of the person to whom they report, not of the person they monitor.

Further, the panel is concerned about the undermanning of the QA offices in the regions as well as in the assistant administrator's office. Clearly, this diminishes the confidence that can be placed by the administrator in the programs. The very existence of part-time QA officers at the regional level reflects the confusion of QC and QA discussed in Section I. Part-time QA officers have divided loyalties even outside QA or QC and cannot provide the protection or advice that independent, skilled QA personnel should be giving. Carrying this point further, the panel recommends that at all levels the responsibilities for the application of QA/QC procedures be assigned in ways such that conflicts of interest are minimized.

At this point in the panel's review of the EPA's QA program, the panel does not wish to give precise recommendations to the Administrator regarding expenditures on QA since it does not yet have the necessary information regarding staff and budget to judge properly the present support for the QA program. It has been the experience of experts in private firms that about 0.5 percent of the total cost of a technical project should be spent for QA. This figure could serve as a guide for EPA in budgeting for its QA program.

As an aid to QA management (and, incidentally to the panel in its formulation of useful final recommendations to the Agency,) it would be useful for the Agency to compile some concise information on QA personnel and their roles and responsibilities in the QA program.

1. A list should be maintained for the officer responsible for QA of all employees of the Environmental Protection Agency and its associated laboratories and agencies who have responsibilities in any aspect of the QA program (site visits to check the QA procedures in contract laboratories, etc.). This list should indicate the educational degrees and previous experience of the personnel shown and the percentage of their time spent on QA activities, and assigned responsibilities to other offices.

2. An organizational chart of the QA personnel is important to the effective operation of the QA program. This should be prepared by the EPA administration and should designate clearly to whom each QA officer reports and from whom the money to support his or her position is received. The relationships (lines of reporting), if any, between the QA officers within the Agency's major laboratories, regional offices and laboratories, and the enforcement branches such as the National Enforcement and Investigations Center (NEIC) must be delineated.

3. At times of environmental crisis, it is essential that funds be available to the appropriate EPA office or laboratory to formulate the special QA/QC plans that will allow the collection of relevant and meaningful data to answer the needs as defined by the administrator or his or her deputy. As discussed in Section I, the panel recommends that a special emergency QA panel of experts be maintained on call, to be convened at time of crisis, to establish the necessary sampling and analytical protocols that will assure the quality of the data to be collected. It is at times like this that those responsible for QA may be especially helpful in advising on QC. Perhaps the present EPA contractors and consultants could be among those who serve in this

capacity, although their role as advisor may be compromised by self-serving interests for further work. It is important to establish the degree of precision necessary in the particular measurements, so as not to choose methods that result in wasteful overkill. Obviously, very precise analyses of large cost will be required for some cases, and less expensive, less precise analyses will do for others.

QAMS itself is beginning to function well now. However, a more effective QA program in EPA might result from placing a national office for QA in the EPA's Table of Organization, as opposed to the current situation where visibility and clout are lacking because QAMS is a small activity in the Office of Exploratory Research under the Office of Research and Development (ORD). Putting QAMS in the Table would help assure, as well as emphasize, its importance to all of the EPA regulatory activities. Centralization and unification of basic principles, methods, procedures, and criteria could more easily issue from above to the QA officers and their program, regional, or divisional activities. As the role of QAMS shifts from program development to the highest level of auditing, it can monitor the QA program and its own performance can be examined for effectiveness.

There are many compelling reasons for the preparation of nationally applicable documents relevant to required scientific data practices and the conduct of a sound QA program. For example, a national QA/QC Superfund volume could give better direction to regional activities in solid waste and toxics and would eliminate the need for regional offices to develop their individual (and differing) guidelines, such as were shown to panel members in visits to their regions. Wasteful incompatibilities among data sets originating from different regions would thus be reduced. Further, such a centralization of the preparation of nationally applicable documents may alleviate the situation described aptly by one panel member as the writing "of documents about documents," characteristic of the overwriting that one does when one's ideas are unclear. Often, such volumes produced by small in-house groups do not provide guidelines that reflect the cutting edge of present-day wisdom. In all fairness, some of EPA's documents presented to the panel display the Agency's use of most current well-grounded statistical methods, for which the Agency clearly deserves commendation. It would be advisable for EPA to draw on the most knowledgeable and substantial talent in and outside of EPA to develop such documents.

Generally, the panel has observed that there appear to be no strategies whatsoever for establishing statistically valid procedures for field collections. Samples are sometimes taken without having properly developed a statistically valid sampling design; rationales for locating sampling or monitoring stations are likewise often without logical underpinning. This is not only ineffective, but costly. Documentation of the strategy of sampling, not the tactics, would be extremely helpful, especially if it were reviewed and revised roughly every five years.

*In summary, the panel feels that the EPA administration must insure that a firm and realistic budgetary commitment is provided to support the quality assurance program so that well-qualified personnel can be attracted into the quality assurance officer program and the necessary standards of an excellent quality assurance program can be supported. The amount of commitment should be guided in the interim by the private sector's policy that the expenditure on QA should be about 0.5 percent of the total operating costs of the office or laboratory.*

*The panel also recommends that the quality assurance program see to it that nationally applicable documents regarding data measurement, recording, and handling as well as QA procedures are generated by qualified persons and made widely available to the branches of the Agency and to its contractors.*

*A last but also important recommendation of this interim report is that the EPA take care to assign QA responsibilities to staff that has competence in this specialized task and has no other assignments that pose conflicts of interest.*

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REMARKS:

ADDITIONAL: NO FUNCTION CODE: